UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

KEALANI DISTRIBUTION LLC, ET AL.	§	
	§	
v.	§	CIVIL NO. 4:22-CV-856-SDJ
	§	
FOOD AND DRUG ADMINISTRATION, ET AL.	§	

MEMORANDUM OPINION AND ORDER

When a federal agency promulgates a rule, the Regulatory Flexibility Act ("RFA") requires the agency to either analyze how the rule will affect small businesses or certify that the rule will not have a "significant economic impact on a substantial number of small entities." 5 U.S.C. §§ 603–604, 605(b). The requirements of the RFA are "purely procedural" and impose "no substantive constraint on agency decisionmaking." *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) (internal quotation marks and alteration omitted). An agency need only demonstrate a "reasonable, good-faith effort to carry out RFA's mandate." *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001) (citation and alteration omitted).

Plaintiffs here include several small businesses that manufacture "e-liquids"—the nicotine-containing liquid in e-cigarettes—and a trade association (collectively, the "Manufacturers").[1] They challenge the FDA's certification for a 2021 regulation

[1] Plaintiffs include Kealani Distribution LLC, Diamond Vapor LLC, Johnny Copper LLC, SWT Global Supply, Inc., Carolina Vapor Mill LLC, Carolina Vapor Mill Woodruff Road, CVM3 LLC, and United States Vaping Association, Inc.

(the "2021 Final Rule")[2] that clarifies the requirements for Premarket Tobacco Applications ("PMTA"). The FDA counters that its certification is proper.

Before the Court are Plaintiffs' Motion for Summary Judgment, (Dkt. #36), and Defendants' Cross Motion for Summary Judgment, (Dkt. #37). Having considered the parties' briefing, the administrative record, and the applicable law, the Court concludes that the FDA made a reasonable, good-faith effort to comply with the RFA when promulgating the 2021 Final Rule. Accordingly, Plaintiffs' Motion for Summary Judgment will be **DENIED**, and Defendants' Cross Motion for Summary Judgment will be **GRANTED**.

I. BACKGROUND

A. The FDA's Authority to Regulate Tobacco

The FDA first attempted to regulate tobacco three decades ago. In 1995, it proposed a rule to regulate the sale of cigarettes and smokeless tobacco to children.[3] In support, the FDA cited several findings on the harmful effects of cigarette smoking and the addictiveness of nicotine.[4] A year later, the FDA finalized the rule,[5]

[2] Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55300 (Oct. 5, 2021) (the "2021 Final Rule").

[3] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41314 (Aug. 11, 1995).

[4] Some of these findings included that (1) tobacco use was the single leading cause of preventable death in the United States, *id.* at 41361; (2) more than 400,000 people died each year from tobacco-related illnesses, *id.*; and (3) "[c]igarettes kill more Americans each year than acquired immune deficiency syndrome (AIDS), alcohol, car accidents, murder, suicides, illegal drugs, and fires combined," *id.* at 41314.

[5] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44396, 44397–99 (Aug. 28, 1996).

concluding that it could regulate tobacco under the Federal Food, Drug, and Cosmetic Act ("FDCA") because the "nicotine in cigarettes and smokeless tobacco is a 'drug.'"[6]

Several tobacco companies successfully challenged the FDA's conclusion in federal court. In *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court held that "Congress ha[d] clearly precluded the FDA from asserting jurisdiction to regulate tobacco products." 529 U.S. 120, 126, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000). For nearly a decade thereafter, the FDA did not assert—and Congress did not convey—the power to regulate tobacco products.

But in 2009, Congress empowered the FDA to regulate the sale and marketing of tobacco products by amending the FDCA through the Family Smoking Prevention and Tobacco Control Act ("TCA"). Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387, *et seq*.). Congress recognized that prior efforts to regulate tobacco products "ha[d] failed adequately to curb tobacco use by adolescents," *id*. § 2, 123 Stat. at 1777, and found that "[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," *id*. Based on these and related findings, Congress determined that "comprehensive restrictions on the sale, promotion and distribution of [tobacco] products [we]re needed[.]" *Id*. To enforce such restrictions, the TCA vests the FDA with broad authority to address "the public health and societal problems caused by the use of tobacco products." *Id*.

[6] *See id*. at 44397.

Along with provisions enabling the FDA to regulate tobacco products, the TCA imposes several requirements on tobacco-product manufacturers. Relevant here, the TCA prohibits manufacturers from marketing or selling any "new tobacco product"[7] without first receiving FDA approval.[8] 21 U.S.C. § 387j(a)(2)(A)–(B). A "new tobacco product" is one that was "not commercially marketed in the United States as of February 15, 2007," or any modified version of a tobacco product marketed after that date. *Id.* § 387j(a)(1)(A)–(B).

To obtain FDA approval for a new tobacco product, a manufacturer must receive premarket authorization from the agency. The premarket-authorization process begins when a manufacturer submits a PMTA. *Id.* § 387j(b). The PMTA must include "full reports of all information . . . concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products." *Id.* § 387j(b)(1)(A). PMTAs must also include "a full statement of the components, ingredients, additives, and properties" of the tobacco product; "the methods used in, and the facilities and controls used for, the manufacture" of the product; "specimens of the labeling proposed to be used" for the product; and "such other information . . . as the Secretary may require." *Id.* § 387j(b)(1)(B)–(C), (F)–(G).

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[7] Under the TCA, "tobacco products" include "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and . . . any other tobacco products that the Secretary [of Health and Human Services] by Regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b).

[8] While the TCA has a grandfather provision, the parties agree that the e-liquid products at issue here do not fall under it.

The FDA examines PMTAs for information about the product's "risks and benefits to the population as a whole," evaluating the "likelihood that existing users of tobacco products will" quit or significantly reduce their use of more harmful tobacco products and the "likelihood that those who do not use tobacco products will start." *Id.* § 387j(c)(4). The FDA's ultimate conclusion "shall, when appropriate, be determined on the basis of well-controlled investigations" and other "valid scientific evidence." *Id.* § 387j(c)(5)(A)–(B). The TCA provides that the FDA "shall deny" an application to market a new tobacco product unless the agency finds that, based on "the information submitted to the [FDA] as part of the application and any other information before the [FDA] with respect to such tobacco product, . . . permitting such tobacco product to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(c)(2).

B. The Deeming Rule Extends the FDA's Authority Over E-liquids

The TCA authorizes the FDA to deem new tobacco products that enter the market to be subject to the Act's requirements. *Nicopure Labs, LLC v. FDA ("Nicopure II")*, 944 F.3d 267, 272 (D.C. Cir. 2019) (citing 21 U.S.C. § 387a(b)). The FDA exercised this authority in 2016 when it published the Deeming Rule,[9] which brought e-liquids, among other tobacco products, under the TCA. In support, the FDA cited concerns with "the dramatic rise in [Electronic Nicotine Delivery System] use among youth,"

[9] Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28974, 28974 (May 10, 2016) ("Deeming Rule").

which included (1) an "800 percent" increase between "2011 and 2014" in e-cigarette use "among high school students," combined with (2) a three-fold increase "between 2011 and 2013" in "the number of never-smoking youth who had reported ever using an e-cigarette . . . from 79,000 to more than 263,000 youth." Deeming Rule, 81 Fed. Reg. at 29028–29 (quotations omitted). As a result, these now-deemed tobacco products became subject to the TCA's premarket-authorization process.

The Deeming Rule created concern among e-liquid manufacturers. Without FDA approval, they could be precluded from both marketing and selling e-liquids and e-cigarettes.[10] The cost of compliance was particularly worrying to manufacturers, and smaller companies complained that they could not afford to conduct and prepare the statutorily required studies for their PMTAs. (Dkt. #36 at 18–19). Such health-risk investigations, even without long-term clinical studies, are inherently expensive to produce.[11] And the FDA itself, through the Deeming Rule Final Regulatory Impact Analysis ("Deeming Rule RIA"),[12] predicted that the Deeming Rule would "have a significant economic impact on a substantial number of small entities." Deeming Rule RIA at 4. The FDA estimated that for each small e-cigarette manufacturer, the cost

[10] E-liquid manufacturers with products already on the market had a grace period to comply with the premarket-review process. Deeming Rule, 81 Fed. Reg. at 28978. But all e-liquid applicants had to comply by 2020. *See generally In re Cigar Ass'n of Am.*, 812 F.App'x 128, 133 (4th Cir. 2020).

[11] *See, e.g.*, U.S. Small Business Administration Office of Advocacy, Comment Letter on Premarket Tobacco Product Applications and Recordkeeping Requirements (Nov. 27, 2019) ("SBA Advocacy Comment"), https://advocacy.sba.gov/wp-content/uploads/2019/11/Advocacys-PMTA-Comment-Letter.pdf.

[12] U.S. Food & Drug Admin., Deeming Rule Final Regulatory Impact Analysis (May 2016), https://www.regulations.gov/document/FDA-2019-N-2854-0125.

of premarket review would be roughly $814,000 to $1.1 million. *Id.* at 133. The FDA also estimated that "between 50 and 87.5 percent of e-liquid[] [manufacturers] will not submit a marketing application and will exit the market after the initial compliance period for the submission and FDA receipt of PMTAs ends." *Id.* at 79.

The e-cigarette industry responded to the Deeming Rule with an array of litigation, challenging its validity under both the Constitution and the Administrative Procedure Act ("APA"). Several courts, including the Fifth Circuit, rejected these challenges and upheld the Deeming Rule. *See, e.g.*, *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 444 (5th Cir. 2020) (holding that the FDA's deeming authority did not violate the nondelegation doctrine), *cert. denied*, 141 S.Ct. 2746, 210 L.Ed.2d 896 (2021); *Nicopure II*, 944 F.3d at 273–76, 281–82 (D.C. Cir. 2019) (rejecting APA challenge and holding that the Deeming Rule was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).

C. The 2021 Final Rule and the Manufacturers' Suit

While the litigation challenging the Deeming Rule was ongoing, the FDA continued to develop the PMTA requirements for the e-cigarette industry. Between 2017 and 2019, the FDA repeatedly interacted with the e-cigarette industry by issuing guidance documents, making public statements, and holding public meetings. *See* (Dkt. #36 at 9–12) (detailing several of these actions that related to PMTA guidance); *see also Wages and White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 364–66 (5th Cir. 2024) (en banc) (same).

In 2019, the FDA proposed a rule that expounded on PMTA requirements. *See* Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50566 (Sept. 25, 2019). The proposed rule would, among other things, "interpret and set forth requirements related to the content and format of PMTAs[.]" *Id.* at 50567. These requirements sought to ensure that each PMTA was submitted with "the threshold amount of information necessary for application filing[.]" *Id.* at 50567. The proposed rule also sought to "codify the general procedures FDA would follow when evaluating PMTAs, including application acceptance, application filing, and inspections, and would also create postmarket reporting requirements for applicants that receive marketing orders." *Id.*

After reviewing public comments, the FDA published the 2021 Final Rule. The agency concluded that the rule would provide useful, cost-saving clarity for the affected entities. 86 Fed. Reg. at 55302. The 2021 Final Rule achieves this by making the application process more predictable: it clarifies PMTA content and format requirements, standardizes the FDA's review process, and establishes document-retention policies. *Id.* at 55400. Because the FDA expected the rule to "generate net benefits or negligible net costs for most affected small entities," it certified "that the final rule will not have a significant economic impact on a substantial number of small entities." *Id.*

In support of this certification, the FDA provided a final regulatory impact analysis ("2021 Final Rule RIA").[13] Among other things, the 2021 Final Rule RIA

[13] U.S. Food & Drug Admin., *PMTA and Recordkeeping Requirements Final Regulatory Impact Analysis* (November 2022).

differentiated between the costs imposed by the Deeming Rule and those imposed by the 2021 Final Rule. 2021 Final Rule RIA at 7–9. The FDA noted that the Deeming Rule "extended FDA's regulatory authority to all tobacco products," which meant that "all premarket requirements appl[ied] to deemed new tobacco products." *Id.* at 12. Because of the significant compliance costs associated with these requirements, the FDA predicted that many "small firms" would "exit the market or merge with other firms." *Id.* at 42. Reaffirming its position from the Deeming Rule RIA, the FDA expected "the Deeming Rule to have a significant impact on a substantial number of small entities." *Id.*

By contrast, the FDA believed that the costs imposed by the 2021 Final Rule's new content and format requirements would be "negligible" for "most affected small entities." *Id.* at 7, *see also id.* at Table 24 (comparing the estimated cost to compile a PMTA before and after the Final Rule). Although the FDA acknowledged that the 2021 Final Rule introduced "some new requirements for PMTAs" that would "[i]ncreas[e] the administrative effort required to organize and prepare a PMTA," *id.* at 26, the agency predicted that these modest cost increases would be offset by savings and increased profits for most affected entities, *id.* at 44. As explained by the FDA, the cost savings would flow from a clarified and streamlined review process, which would help applicants avoid costly supplemental applications. *See id.* at 16 (discussing the goal of avoiding applicant "trial and error"). The agency concluded that, with more streamlined review under the 2021 Final Rule, applicants could

expect to obtain marketing orders—and thus revenue from their new tobacco products—more quickly. *Id.*

For all these reasons, the FDA published the 2021 Final Rule and certified that it would not have a significant impact on a substantial number of small entities. *Id.* at 44.

In response, the Manufacturers sued the FDA, claiming that the 2021 Final Rule violated the RFA. (Dkt. #1). The Manufacturers' claim is a narrow one: they assert that the FDA's "certification of no significant impact on a substantial number of small entities is erroneous on its face." (Dkt. #1 ¶ 60); *see also* (Dkt. #1 ¶¶ 61–66) (reiterating the Manufacturers' position that the certification is factually erroneous and maintaining that the 2021 Final Rule "has a significant impact on a substantial number of small entities"). The Manufacturers and the FDA have filed cross motions for summary judgment on whether the 2021 Final Rule violated the RFA. (Dkt. #36, #37). The motions are fully briefed and ripe for review.

II. LEGAL STANDARD

In general, "[s]ummary judgment is appropriate only when 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Shepherd ex rel. Shepherd v. City of Shreveport*, 920 F.3d 278, 282–83 (5th Cir. 2019) (quoting FED R. CIV. P. 56(a)). But "in cases involving review of agency action under the Administrative Procedure Act, Rule 56 does not apply due to the limited role of a court in reviewing the administrative record." *Nicopure Labs, LLC v. FDA* ("*Nicopure I*"), 266 F.Supp.3d 360, 379 (D.D.C.

2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019). Instead, "[s]ummary judgment . . . serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Hi-Tech Pharmacal Co. v. FDA*, 587 F.Supp.2d 13, 18 (D.D.C. 2008). If the Court finds that an agency action was "arbitrary, capricious, or otherwise not in accordance with law," the Court must "hold unlawful and set aside" that action. 5 U.S.C. § 706(2)(A).

Under the RFA, district courts have jurisdiction to review "agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7 [of the APA]." 5 U.S.C. § 611(a); *see also Associated Fisheries of Me., Inc. v. Daley*, 127 F.3d 104, 112 (1st Cir. 1997). At the summary-judgment stage, the proper inquiry of this review is "only to determine whether an agency has made a 'reasonable, good-faith effort' to carry out the mandate of the RFA." *Alenco Commc'ns, Inc. v. FCC,* 201 F.3d 608, 619–20 (5th Cir. 2000) (quotations omitted). Indeed, the RFA "is a procedural rather than substantive agency mandate." *Id.* at 625. Thus, the court's review is deferential. *See, e.g.*, *Zero Zone, Inc. v. U.S. Dep't of Energy*, 832 F.3d 654, 683–84 (7th Cir. 2016) (finding that the Department of Energy made a "reasonable, good-faith" effort to consider alternatives to energy-efficient manufacturing rulemaking); *U.S. Cellular Corp.*, 254 F.3d at 88–89 (finding that the FCC made a reasonable, good-faith effort to follow the RFA by publishing a final RFA analysis).

III. DISCUSSION

A. RFA Requirements and Exceptions

The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 864 (1996) (codified as amended at 5 U.S.C. §§ 601–612), requires an agency to identify the potential economic impact of proposed and final rules on small entities that will be subject to the rule's requirements. Congress passed the RFA in response to concerns with the burdens of federal regulation, especially on small businesses. *See generally* Paul R. Verkuil, *A Critical Guide to the Regulatory Flexibility Act*, 1982 DUKE L.J. 213 (1982).

Relevant here, the RFA requires agencies that issue rules under the APA to publish a final regulatory flexibility analysis. *See* 5 U.S.C. § 604. Such analyses must include several components, including a statement of the need for the rule, the agency's response to any significant comments, an estimate of the number of small entities to which the rule will apply, a description of the rule's compliance requirements, and a description of the steps the agency has taken to minimize the economic impact on small entities. *Id*. § 604(a)(1)–(6). In practice, an agency meets these requirements by publishing its rules with a regulatory impact analysis. *See generally* Maeve P. Carey, CONG. RSCH. SERV., IF12058, *Cost-Benefit Analysis in Federal Agency Rulemaking* (March 8, 2022). Alternatively, an agency can bypass these requirements if the rule qualifies for an exception. Section 605(b), for example, provides an exception when the "head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small

entities." This certification must be published in the Federal Register simultaneously with the rule. 5 U.S.C. § 605(b).

Because the RFA imposes only procedural requirements, judicial review is limited to whether an agency followed the proper procedure while promulgating its rule. *See, e.g.*, *Nicopure I*, 266 F.Supp.3d at 408 (noting that the RFA "simply requires agencies to publish analyses that address specific topics," and when they do so, they have "complied with the [RFA]"). As the Fifth Circuit has recognized, because the RFA is "a procedural rather than substantive agency mandate," it does not prohibit agencies from promulgating regulations that impose broad economic impacts on small entities. *Alenco*, 201 F.3d at 625. Rather, the RFA requires "agencies to engage in a reasonable, good-faith effort to carry out the statute's mandates." *Associated Gen. Contractors of Am. v. DOL*, No. 5:23-CV-0272, 2024 WL 3635540, at *15 (N.D. Tex. June 24, 2024) (citing *U.S. Cellular Corp.*, 254 F.3d at 88) (quotations omitted).

B. Analysis of the 2021 Final Rule

The Manufacturers' challenge to the 2021 Final Rule fails for two reasons. First, the FDA satisfied the RFA by considering whether the 2021 Final Rule would have a significant impact on a substantial number of small entities and certifying, together with a factual basis, that it would not. Second, the Manufacturers have failed to identify any procedural defect in the FDA's certification. Instead, Manufacturers raise only substantive disagreements with the FDA's factual basis, which are outside the scope of RFA review.

i. The FDA met the RFA's requirements for the 2021 Final Rule.

The Manufacturers' RFA claim fails at the outset because the record shows that the FDA followed the RFA's procedural requirements for the 2021 Final Rule. The agency "publish[ed] [its] certification in the Federal Register" with the 2021 Final Rule and offered "a statement providing the factual basis for such certification." 5 U.S.C. § 605(b). As described herein, the 2021 Final Rule RIA explained that the significant costs associated with submitting PMTAs were traceable to the Deeming Rule. *See supra* Part I.C. The FDA further concluded that the costs imposed by the 2021 Final Rule's new administrative requirements would be incremental and modest compared to the baseline costs already imposed on small manufacturers by the Deeming Rule. *Compare* Deeming Rule RIA at 133 (estimating compliance costs for each small manufacturer to be between $814,000 and $1.1 million), *with* Final Rule RIA at 44 (estimating that most small entities would either "benefit from the final rule or will incur small annualized costs of approximately $2,000"); *see also supra* Part I.C. The RFA was therefore satisfied. *See, e.g.*, *Nat'l Rest. Ass'n v. Solis*, 870 F.Supp.2d 42, 60 (D.D.C. 2012) (explaining that because the RFA's requirements are "purely procedural," an agency "complied . . . when it concluded that . . . the rule would not have an impact on a substantial number of small entities" and provided a factual basis).[14]

[14] Because the FDA's 2021 Final Rule complied with the RFA, the Court does not reach the parties' arguments about remedies.

ii. The Manufacturers' contention that the FDA's factual basis was erroneous is outside the scope of RFA review.

The Manufacturers fail to identify any procedural flaw in the FDA's certification. Although the Manufacturers suggest that the FDA did not provide a factual basis for certification, this conclusory statement is belied by their simultaneous acknowledgment of—and dispute with—aspects of the FDA's factual analysis. *See* (Dkt. #36 at 16–17) (arguing on one hand that the agency "lacks any factual basis for the certification," while at the same time disagreeing with the substance of the agency's factual basis for certification). In any event, the Manufacturers' disagreement with the FDA's analysis of certain factual issues underlying its certification "does not mean that the [FDA] failed to meet its obligations [under the RFA] to examine and discuss" those facts in support of its certification. *ValueVision Int'l, Inc. v. FCC*, 149 F.3d 1204, 1213 (D.C. Cir. 1998).

Turning to their claim that the certification is erroneous, the Manufacturers take issue with the FDA's attribution of PMTA-related costs to the Deeming Rule—a *substantive factual conclusion* underlying its certification. In their view, the FDA should have attributed these costs to the 2021 Final Rule because the FDA's original analysis of PMTA-related costs was too preliminary and uncertain. (Dkt. #36 at 7–8); (Dkt. #40 at 3). The costs should have been recalculated, the Manufacturers claim, in the context of "the regulated industry at the time the [2021 Final Rule] was proposed and issued." (Dkt. #40 at 6). On its face, this challenge turns on the Manufacturers' disagreement with the substance of the FDA's factual basis underlying the

Certification, not any procedural defect in the 2021 Final Rule, much less a defect that runs afoul of the RFA.

In short, the Manufacturers' claim that the FDA's factual basis for the certification of the 2021 Final Rule was erroneous or otherwise substantively flawed is not a procedural attack cognizable under the RFA. *See Council for Urological Ints. v. Burwell*, 790 F.3d 212, 227 (D.C. Cir. 2015) (holding that an agency's statement of belief as to a rule's impact satisfied Section 605(b)'s requirements, even though plaintiff argued that this belief was "incorrect"); *Grocery Servs., Inc. v. USDA Food & Nutrition Serv.*, No. H-06-2354, 2007 WL 2872876, at *10 (S.D. Tex. Sept. 27, 2007) (explaining that a challenge to "the factual veracity" of an agency's analysis was "outside the limited scope of judicial RFA review").[15]

[15] The Manufacturers mistakenly rely on two cases in which an agency's certification was factually unsupported. *N.C. Fisheries Ass'n v. Daley* ("*Daley I*"), 16 F.Supp.2d 647 (E.D. Va. 1997); *N.C. Fisheries Ass'n v. Daley* ("*Daley II*"), 27 F.Supp.2d 650 (E.D. Va. 1998). *Daley I* suggests that an agency must have supporting evidence to certify that a regulation will have no economic impact. 16 F.Supp.2d at 653. A "simple conclusory statement," stated the court, "is not an analysis." *Id*. True enough. But the 2021 Final Rule RIA includes *twenty pages of analysis* on the effects of the rule's compliance-related costs. 2021 Final Rule RIA at 21–41. Based on this analysis, the FDA estimated that incremental costs of no more than $2,000 per affected entity would result from the 2021 Final Rule. *Id*. at 44. Several tables and analyses support this estimate. *Id*. at 21–41. Because the FDA's certification is supported by more than a "simple conclusory statement," *Daley I* is inapposite. 16 F.Supp.2d at 653.

Daley II describes an agency that "consciously ignored [its] own data," refused "to recognize the economic impacts of [its] regulatory actions," and suggested that it was "under no statutory duty to consider alternatives." 27 F.Supp.2d at 660–61. As a result, the court found that the agency failed to engage in a good-faith attempt to comply with the RFA's requirement to consider alternatives. *Id*. at 661. There is no such evidence here. Contrary to the Manufacturers' contentions, the FDA did not "avoid[] grappling with the economic impact of the policy choices [it] made[.]" (Dkt. #40 at 3). Rather, it quantified the economic effects of its policy choices through the Deeming Rule RIA and the 2021 Final Rule RIA. Deeming Rule RIA at 128–34; 2021 Final Rule RIA at 21–41. And the 2021 Final Rule RIA provided reasons for selecting the alternative it chose and rejecting the other alternatives. 2021 Final Rule RIA at 40–41. Because the FDA considered alternatives and quantified their costs, the reasoning in *Daley II* does not apply here either.

* * * *

The FDA undertook a good-faith effort to quantify the economic costs imposed on small businesses by the 2021 Final Rule. It found that these costs were incremental or negligible. That finding was reasonable. The FDA thus concluded and certified that the 2021 Final Rule would not impose a significant economic impact on a substantial number of small businesses. The RFA requires nothing more.

IV. CONCLUSION

It is **ORDERED** that Plaintiffs Kealani Distribution LLC, Diamond Vapor LLC, Johnny Copper LLC, SWT Global Supply, Inc., Carolina Vapor Mull LLC, Carolina Vapor Mill Woodruff Road, CVM3 LLC, and United States Vaping Association, Inc.'s Motion for Summary Judgment, (Dkt. #36), is **DENIED**.

It is further **ORDERED** that the FDA's Cross-Motion for Summary Judgment, (Dkt. #37), is **GRANTED**.

It is further **ORDERED** that all claims asserted by Plaintiffs are **DISMISSED with prejudice**.

So ORDERED and SIGNED this 12th day of February, 2025.

SEAN D. JORDAN
UNITED STATES DISTRICT JUDGE